Plasma & Hemoglobin

In January 2013 Validus acquired the Facility Certified Institute. Prior to the purchase FCI and its Certified Facility Program was created to enhance consumer confidence in the feed and food supply. The Plasma and Hemoglobin Certified Facility Program was created to insure that animal plasma and blood products are complying with the Title 21, CFR § 589.2000, Animal Protein Products Prohibited in Ruminant Feed. The program is designed for an independent certifying Auditor to visit facilities which manufacture spray dried animal plasma and blood (hemoglobin) products from avian and mammalian blood. The Auditor will examine and validate guideline procedures, look at records and issue interim certifications to those facilities when an inspection finds the facility meets the program's requirements.

For the purposes of this program, the terms "restricted use mammalian protein products" or "restricted use (protein) products" (RUPP) mean those prohibited mammalian protein products used as feed ingredients within the meaning of the federal regulation governing their use (Title 21, Code of Federal Regulations § 589.2000).

This outline lays out the Plasma and Hemoglobin Certified Facility Program for firms and facilities applying for and receiving facility certifications. The responsibilities of facilities in this program are listed in the certification application (Appendix A), and firms and facilities applying for certification agree to the requirements of this program as described on the application.

Validus reserves the right to alter this program and policies with 30 days notice to the certified facilities. However, changes to the federal regulation (21 CFR, § 589.2000) may necessitate an immediate change in the program. Validus will make every effort to accommodate such federal changes in the program as quickly as possible and notify all certified facilities.

The Program

Facilities complying with the program requirements may apply for and, if certified, receive permission to utilize the Validus seal, logo and label statement for animal plasma certified facilities. A certification seal is authorized for use by certified facilities, and a certificate (Appendix B) and letter are issued to such facilities. Use of the seal, logo and label statements are governed by licensing agreement in Appendix C. Failure to follow the seal and logo placement and use rules for certification may result in decertification.

If the certifying Auditor finds the firm meets the requirements of this program, then the facility will be issued the appropriate certification certificate (Appendix B), subject to annual recertification requirements as described below.

Program Text

Fees

Certifying Inspections

Responsibilities

Confidentiality

Appeals

Program Text

You may download and view a complete outline of the Certified Transport Program (CTP) for firms and facilities applying for and receiving certification. This file is available in the PDF format.

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Fees

Fees are based on the number of locations where records are kept and the number of transportation units (power units) owned and/or operated by the firm. Discounts for multi-location firms are available to AFIA members, provided such firms utilize similar or the same procedures at each location. Validus Agents will perform annual recertification inspections. Failure to remit payment may result in decertification and additional fees for reinstatement. Timely notification will be provided by Validus prior to recertification inspections.

Filing Fee

1.	Application Filing (one-time)	$250	per firm

Inspection Fee

2. Number of Locations

Single Location	$650	
2-10 Locations	$550*	per location
11+ Locations	$450*	per location

3. Number of Transportation Units

Single Unit	$120	
2-10 Units	$60	per unit
11+ Units	$30	per unit

*Only applies to AFIA members and must have one billing address.

Total program fees are determined by adding the fees associated with the one-time application filing, the number of locations, and the number of units.

Upon certification, the firm will be licensed to utilize a Certified Transport Program seal and logo and statements regarding certification under the licensing rules for use and placement of the Certified Transport Program seal (Appendix C). Failure to follow the seal and logo placement and use rules for certification may result in decertification.

Reinspections

Firms not granted certification on the first inspection may request a reinspection. Additional fees may be assessed to cover the costs of the reinspection, but not to exceed the initial fee. The reinspection fee will be determined by the detail level and time resources necessary to reinspect one or all locations. However, the minimum reinspection fee is $500.

Certifying Inspections

Validus uses trained, professional Certifying Agents ("Agents"). Agents are authorized to determine whether a facility is in compliance with the program's rules and grant an interim facility certification in writing at the end of the inspection, subject to review by Validus. Also, the Agent may withhold certification subject to such changes as are suggested by the Agent and agreed to by the firm, in which case, a reinspection may be necessary. Additional inpsections may require additional fees, subject to the details and time, which the reinspection requires. Validus retains the final authority to grant or deny facility certification.

A. Program Requirements

Firms, and their locations, shall possess the following:

1. A written training program to educate employees regarding FDA's Sanitary Food Transportation Act of 1990 and regulation of restricted use protein products. Program to include FDA-CVM video, "Do Your Part"' emphasizing transportation's responsibility in BSE prevention.
2. Written procedures and/or instructions for drivers to account for and document what was previously hauled in a container prior to loading.
3. Written procedures and/or instructions for inspection and adequate cleanout (sweep, air lance, flush, scrape, wash) of containers prior to loading to assure no carry-over of harmful substances.
4. Documentation indication substances previously hauled. Such documentation to be made available to receiving personnel at destination upon request.
5. Documentation indicating inspection and type of cleanout performed. Such documentation to be made available to receiving personnel at destination upon request.
6. Written procedures for securing all container access points, including tarps, after loading (when it is known that the container will be unattended between the time it is loaded and when it reaches its destination). If seals are used, document the seal numbers on shipping papers.
7. Written procedures instructing the use of shipping documents to identify the contents of each compartment, along with an official label for each product. In the case of rail shipments, an official product label must accompany and identify the contents of each compartment, and shipping papers must immediately be mailed or electronically sent to the customer.
8. Written procedures for disposition of damages or torn packages which could contaminate other products. This is critical on bag/bulk combination loads.
9. Employee/driver training log regarding above procedures. Annual refresher training is required for recertification.

B. The Inspection Process

A Certifying Agent will visit firms and their locations requesting certification. The Agent will schedule an appointment with the location's management. Attempts will be made to schedule the inspections expeditiously. The Agent will review facility records to document the firm complying with the program's requirements and complete a Facility Certification Inspection Form (Appendix D).

Records for review will include, but not necessarily be limited to, the list stated in Section IV. A.

If one or more discrepancies or deficiencies are noted, the Agent will complete the form in Appendix E, Certification Inspection Deficiency Form, discuss the discrepancies with the location management and leave a copy of the form. Also, the Agent should attempt to get a commitment to change the discrepancies, a specified time to do so, and schedule a reinspection. The Agent should also indicate the approximate costs associated with reinspection, which can be determined by contacting Validus.

Firm and Facility Responsibilities

In order for the certification program to be successful, full cooperation from firms and facilities must be accorded. By signing an application, a firm agrees to allow an Agent of Validus to inspect the firm's facility(ies) and agrees to comply with the provisions of the program detailed on the reverse (or page two) of the certification application.

Responsibilities of Validus in the Program

In order to make the program's operations proceed smoothly and to provide information to facilities about the program, Validus will fulfill the following responsibilities.

A. Validus agrees to operate this program with integrity and provide the most professional services and Agents available
B. Validus agrees to promote and market the Certified Transport Program and develop a website to generate interest in the program and add value to the Certified Transport Program seal.
C. Validus will add to the Certified Facility website the name of each firm certified within three business days following issuance of the certification certificate.
D. Validus agrees to vigorously challenge and pursue legal action against any firm or person using the Certified Transport Program seal and logo, certificate, program statements or promotion in a way which brings disrepute on the program, violates the licensing agreement, is false or misleading, and/or is done by firms not certified by Validus.
E. Validus will provide periodic reports on the program to the certified facilities, government, and other interested parties.

Confidentiality

Validus and its Auditors agree all information provided to Validus for participation in this program, including, but not limited to, applications, reports, procedures, labels, and any other documents, conversations, e-mail or similar information is confidential and may not be disclosed to any other person or organization outside of Validus staff and Auditors without the express written permission of the applicant or certified firm.

Validus will, unless prohibited by law, immediately notify any affected firm or facility of a subpoena, court order, or government agency administrative request for disclosure of any information related to that facility. Validus will coordinate and consult with the affected facility regarding that facility's position on disclosure of the requested information. Validus will take such legal steps as are necessary to either resist production of the information to a third-party, or provide such information only after obtaining, in consultation with the affected facility, an appropriate confidentiality and protective order.

Internal Appeals Procedure

A. Commencing The Appeal

Where a facility disagrees with a Certifying Agent who has rendered a decision after conducting a certifying inspection, the Agent shall contact Validus and discuss the issue. Where the issue cannot be resolved, Validus shall contact another Certifying Agent and arrange for reinspection of the facility.

As soon as possible, the second Certifying Agent shall inspect the facility using the same criteria as the Agent who conducted the original certifying inspection. The second agent may allow the facility or the original Certifying Agent to provide any additional and relevant information.

The second Certifying Agent shall report back to an Appeals Committee when all relevant information has been gathered, and shall turn over all relevant information to the Appeals Committee.

B. The Appeals Committee

The Appeals Committee shall consist of the Validus Chairperson and at least one other Board Member.

The Appeals Committee may be comprised of up to three members.

Every member of the Appeals Committee shall be and remain independent of the parties involved in the appeals process.

C. Appeals Proceedings

The Appeals Committee may deliberate at any location it considers appropriate.

In all cases, the Appeals Committee shall act fairly and impartially and ensure that each party has a reasonable opportunity to present its case.

The Appeals Committee shall proceed within as short a time as possible to render a final decision by all appropriate means.

The Appeals Committee shall take measures for protecting trade secrets and confidential information.

When all relevant information has been presented, the Appeals Committee shall declare the proceedings closed. Thereafter, no further submission or argument may be made, or evidence produced, unless requested or authorized by the Appeals Committee.

D. Decisions

A Decision is rendered by majority vote. If there is no majority, the Decision shall be made by the chairman of the Appeals Committee.

The Decision shall state the reasons upon which it is based.

Once a Decision has been made, all parties shall be notified.

Every Decision shall be binding on the parties. By submitting the dispute to the appeals process, the parties agree to execute a Decision without delay.

E. Miscellaneous

A party that proceeds with the appeals process without raising its objection to a failure to comply with any of these procedures or any direction given by the Appeals Committee shall be deemed to have waived its right to object.

Neither the Appeals Committee members, not Validus, shall be liable to any person for any act or omission in connection with the appeals process.

In all matters not expressly provide for in these procedures, the Appeals Committee shall act in the spirit of these procedures and shall make every effort to determine that the Award is enforceable at law.